

REMARKS/ARGUMENTS

STATUS OF THE CLAIMS

Claims 1-24 are pending. In light of the following, Applicants respectfully request reconsideration and allowance of the pending claims.

CLAIM REJECTION – 35 U.S.C. § 103

Independent Claim 1

Claim 1 stands rejected under 35 U.S.C. § 103(a) as being anticipated by U.S. Patent No. 6,304,777 issued to Ben-Haim et al. (“Ben-Haim”) in view of Medtronic WO 97/40885 (“the Medtronic Reference”).

Claim 1 specifies “a nerve stimulator in communication with the sensor to inhibit beating of a heart when an escape beat is imminent.”

Ben-Haim teaches an apparatus 18 for inducing cardioplegia of a patient’s heart 20. *Ben-Haim*, col. 5, lines 44-60. A control unit 90 conveys electrical energy to electrodes 100 in order to substantially stop motion of the heart 20. The control unit 90 subsequently terminates application of the energy to enable the heart to beat again. *Id.* at col. 6, lines 54-57. Motion sensors 70 are coupled to the heart and send signals to a motion analysis unit 80 of the control unit 90. The signals provide feedback to the control unit 90, which adjusts some or all of the electrical stimuli. The motion sensors 70 allow the control unit 90 to calibrate the electrical stimuli which it delivers to the heart in order to minimize the heart’s motion. *Id.* at col. 7, lines 34-42. The control unit 90 continuously reports the measurements of the sensors 70 to an operator of the apparatus 18, who interprets the measurements. *Id.* at col. 5, lines 61-64. The operator may choose to continue the cardioplegia-inducing procedure, modify the procedure, or terminate the induction of cardioplegia. *Id.* at col. 5, line 64 to col. 6, line 3. Ben-Haim also teaches that an arrhythmia detection unit 82 of the control unit 90 receives inputs from sensors

70 and 72 and from electrodes 74 and 100, so that the control unit 90 can treat or terminate an arrhythmia. *Id.* at col. 8, lines 15-23.

If the control unit 90 of Ben-Haim is the “nerve stimulator” of Claim 1, the control unit 90 does not inhibit the beating of the heart specifically when an escape beat is imminent. Ben-Haim does not teach that the sensors 70 and the control unit 90 are used to determine when an escape beat is imminent. Rather, the sensors 70 only allow the control unit 90 to calibrate the electrical stimuli in order to generally minimize the heart’s motion. *Id.* at col. 7, lines 40-42. Ben-Haim does not teach that the control unit 90 specifically detects and prevents imminent escape beats.

The Medtronic Reference does not cure the deficiencies of Ben-Haim. The Medtronic Reference teaches a control panel 14 that is divided into a heart stimulation control area 15 and a heart destimulation control area 17. *The Medtronic Reference*, page 5, lines 23-24. A stimulation switch 24 can be pressed to initiate heart stimulation, while a destimulation switch 26 can be pressed to initiate heart destimulation. A foot pedal assembly 30 can be used as an alternative to the switches 24, 26. *Id.* at page 6, lines 1-7. A first pair of electrodes 37 and 38 supply electrical current from an electrical control device 50 to the heart during stimulation and destimulation. *Id.* at page 6, lines 17-19. Using the electrodes 37 and 38, the electrical control device 50 applies either a series of current pulses or a burst pulse width to the heart to stop the heart from beating. *Id.* at page 8, lines 20-28.

If the destimulation switch 26 and the electrical control device 50 of the Medtronic Reference are the “nerve stimulator” of Claim 1, the destimulation switch 26 and the electrical control device 50 do not inhibit the beating of the heart specifically when an escape beat is imminent. First, the Medtronic Reference does not teach determining when an escape beat is imminent. Second, the surgeon 82 must manually press the destimulation switch 26 or the foot pedal assembly 30 to stop the heartbeat. *Id.* at page 9, lines 11-15.

Claim 1 also specifies “the nerve stimulator being off whenever the cardiac stimulator is on and the cardiac stimulator being off whenever the nerve stimulator is on.”

Ben-Haim specifically teaches away from having the cardiac stimulator off when the nerve stimulator is on. Ben-Haim teaches that standard pacing signals, delivered by the electrodes 100 are continued throughout most or all of the surgical procedure. Ben-Haim also teaches that application of the pacing signals is believed to help the heart maintain order in regions which are not directly affected by the cardioplegia-inducing signals. Ben-Haim further teaches that continued application of the pacing signals may help improve the heart's recovery from the cardioplegic period by decreasing the time before normal beating resumes. *Ben-Haim*, col. 9, line 58 to col. 10, line 4.

The Medtronic Reference does not cure the deficiencies of Ben-Haim. The Medtronic Reference teaches that the surgeon may wish to stop the heartbeat while making stitches where movement of the heart would normally be a hindrance. The heart may then be stimulated either naturally or artificially through the apparatus 18 to beat for a predetermined time to permit blood flow throughout the body and then be destimulated or stopped again to continue stitching. *The Medtronic Reference*, pages 9, lines 13-18. The Medtronic Reference does not teach any coordination between the stimulation switch 24 and the destimulation switch 26. Rather, the Medtronic Reference only teaches a way of manually changing the current path with the switches 24, 26 or the foot pedal assembly 30 to stimulate or destimulate the heart. In addition, with the apparatus 18 taught by the Medtronic Reference, both the stimulation switch 24 and the destimulation switch 26 could be closed by the surgeon at the same time.

In light of the above, neither Ben-Haim nor the Medtronic Reference, either alone or in combination, teaches or suggests "a nerve stimulator in communication with the sensor to inhibit beating of a heart when an escape beat is imminent" or "the nerve stimulator being off whenever the cardiac stimulator is on and the cardiac stimulator being off whenever the nerve stimulator is on," as specified by Claim 1. Therefore, independent Claim 1 and dependent Claims 2-24 are allowable.

Dependent Claims 2-24

Claims 2-24 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ben-Haim in view of the Medtronic Reference. Claims 2-24 depend from Claim 1 and are therefore allowable for the reasons set forth above with respect to Claim 1. Claims 2-24 specify additional patentable subject matter not specifically discussed herein.

CONCLUSION

In light of the above, Applicants respectfully request reconsideration and allowance of pending Claims 1-24.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "C. Austin", enclosed within a hand-drawn oval.

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